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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,072	07/03/2003	David Lewis	239775US0DIV	3477

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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
HAGHIGHATIAN, MINA	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 09/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/612,072	LEWIS ET AL.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07/03/03*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Interference

Applicant's submission of a 37 CFR 1.607 request for an interference with U.S. Application No. 10/176,851 (publication No. 20030053957 A1) is acknowledged. However as the instant claims are not in condition for allowance at this time, such request is not granted.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11, 14-15 and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Rovee et al (4,185,100).

Rovee teaches a pharmaceutical composition for topical treatment of skin disorders comprising an anti-inflammatory corticosteroid. The suitable corticosteroids include triamcinolone acetonide (col. 2, lines 62-68). The solvents include ethanol and propylene glycol (col. 3, lines 25-26 and tables A and F). The suitable anti-oxidants include butylated hydroxytoluene (col. 4, lines 41-44; col. 5, lines 45-47). Table F discloses propellant for aerosol formulations.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11, 15-23, are rejected under 35 U.S.C. 103(a) as being unpatentable over Keller et al (WO 9834595).

Keller teaches medical aerosol formulations which comprise an active agent, a propellant mixture, a cosolvent and other optional additives. The suitable active agents include budesonide available in an amount of from 0.001 to 5% by weight (page 16, line 2 and page 17, line 30 to page 18, line 2). The preferred cosolvents, which are particularly advantageous in the solution formulations, include ethanol and propylene glycol which are generally available in an amount of 0.1 to 30% by weight (page 19, lines 11-28 and claims). The propellants include HFA 134a and HFA 227, generally available in an amount of at least 64% (claim11). Keller discloses use of vitamin E in the formulation (as an active agent).

Keller also discloses that the active agent can be used in a pharmaceutically acceptable salt form (page 17, lines 26-29).

Although Keller does not disclose use of vitamin E as an antioxidant however, Keller discloses their use in the formulation. Vitamin E is a known antioxidant and thus preparing such formulations would have been a logical extension of the teachings of

Keller, and that said modifications would have been obvious to one of ordinary skill in the art.

Claims 11, 16-19, 21-23, 26, 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cutie (5,891,419).

Cutie teaches aerosol formulations for oral inhalation containing flunisolide dispersed in HFC 134a and/or HFC 227, and metered dose inhalers suitable for delivering such formulations. Said formulations contain small amounts of ethanol (col. 3, lines 39-42) and antioxidants (col. 4, line 43). Cutie discloses that said formulations are suitable for treating respiratory disorders such as bronchial asthma (col. 3, lines 43-45).

Claims 12-15, 20, 24-25, 27, 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cutie (5,891,419) in view of Radhakrishnan et al (5,192,528).

Cutie, discussed above, lacks disclosure on specific antioxidants and budesonide.

Radhakrishnan teaches corticosteroid inhalation treatment methods of delivering a therapeutic dosage of corticosteroid drug to the lungs. The corticosteroids include flunisolide, budesonide, etc (col. 4, lines 14-25). The formulation (described in example 1) is formed by adding alpha-tocopherol with the corticosteroid and lipids (col. 4, lines 34-37).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made given the general formulations of Cutie for inhalation administration of corticosteroids and antioxidants, to have looked in the art for more specific antioxidants suitable for combination with corticosteroids for inhalation, as taught by Rafhakrishnan, with reasonable expectations of successfully preparing stable and effective formulations. Furthermore it would have been obvious to a person of ordinary skill in the art to have chosen other corticosteroids such as budesonide or other antioxidants such as ascorbyl palmitate.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/244,519. Although the conflicting claims are not identical, they are

not patentably distinct from each other because the examined claims are anticipated by the reference claims. Claims 11-32 are generic to all that is recited in claims of copending Application No. 10/244,519. That is claims of copending Application No. 10/244,519 fall entirely within the scope of claims 11-32, in other words, claims 11-32 are anticipated by claims of copending Application No. 10/244,519. Specifically the composition comprising a corticosteroid, such as budesonide, a propellant such as HFC 134a, a cosolvent such as ethanol and anantioxidant such as tocopherol ester for inhalation of instant claims is the same as the formulation recited in the claims of copending Application No. 10/244,519.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Mina Haghighatian
September 16, 2004